

U.S.S.N. 09/621,092
Filed: July 21, 2000
AMENDMENT AND RESPONSE TO OFFICE ACTION

43. (Amended) The capsule of claim 41 wherein the keying surface is adapted to orient [orients] the capsule within the inhaler.

63 44. The capsule of claim 41 wherein the keying surface identifies the drug to be placed in the capsule.

45. (Amended) The capsule of claim 41 comprising a keying surface on the outside of one end which is adapted to orient [orients] the capsule within the inhaler and a keying surface on the outside of the other end which identifies the drug to be placed in the capsule.

Remarks

Claims 28-30 and 41-45 are pending. Claims 41, 43, and 45 have been amended as discussed below.

Amendments to the Specification

The specification has been amended to shorten the abstract, as requested by the Examiner. No new matter has been added.

Drawings

Applicants have enclosed a copy of page 10 of the formal drawings, including Figures 18 and 19.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 28-30 and 41-45 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

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Claims 41, 43, and 45 have been amended to replace "orients" with "adapted to orient," as suggested by the Examiner.

Rejection Under 35 U.S.C. § 102

Claim 41 was rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,632,971 to Yang. It is unclear to the Applicants, but it appears that the Examiner also rejects dependent claims 28, 30 and 42-45 as being anticipated by Yang. These rejections are all traversed.

U.S. Patent No. 5,632,971 to Yang

Yang describes an empty medicinal capsule including a cap member containing a cap circumferential slot and at least one raised member disposed on the inner surface thereof, and a body member containing a body circumferential slot, whereby the cap member circumferential slot and the body member circumferential slot can be slidably locked with each other. A plurality of raised triangular slots formed on the inner surface of the cap member prevent final locking of the capsule when in a prelocking state and prevents the separation of the cap and body members once the capsule is in a final locking state.

Claim 41 defines a capsule (1) to contain drug for use in an inhaler comprising (2) a keying surface on an outside surface that is (a) adapted to orient the capsule within the inhaler or (b) identifies the drug to be placed in the capsule. Claim 30 defines the capsule of claim 41 further including a medicament. Claim 42, as amended, defines the capsule of claim 41 wherein the keying surface is found on the outside of a closed end of the capsule. Claim 43 defines the capsule of claim 41 wherein the keying surface is adapted to orient the capsule within the

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inhaler. Claim 44 defines the capsule of claim 41 wherein the keying surface identifies the drug to be placed in the capsule. Claim 45 defines the capsule of claim 41 comprising a keying surface on the outside of one end which is adapted to orient the capsule within the inhaler and a keying surface on the outside of the other end which identifies the drug to be placed in the capsule.

Support for the amendment to say that the keying surface is on the outside is found in Figure 7 (element 300).

Yang does not teach a capsule for use in an inhaler comprising a keying surface that orients the capsule within the inhaler or identifies the drug to be placed in the capsule. Yang teaches a medicament capsule wherein raised members are used for locking mechanisms. All raised members in the capsule taught by Yang are formed on the inner surface of the cap member as a means of preventing final locking in a prelocking state and separation of the capsule members after final locking.

Yang nowhere discloses keying surfaces for means of tactile and visual identification of the medicament capsule or correct mating of the medicament capsule with the proper dry particle inhaler.

Therefore Yang does not disclose each element of claims 41-45 and 30.

Claim 28 defines the capsule of claim 41 comprising a first tube and a second tube, wherein:

(a) a first tube having a long axis, having an inner and an outer surface radial to the long axis, wherein the tube is open at one end perpendicular to the long axis and closed at

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one end perpendicular to the long axis; and wherein the first tube has at least one protrusion on its outer surface; and

(b) a second tube having a long axis, having an inner and an outer surface radial to the long axis, wherein the tube is open at one end perpendicular to the long axis and closed at one end perpendicular to the long axis and wherein the second tube has at least one protrusion on its inner surface; and wherein the outer circumference of the first tube is approximately equal to the inner circumference of the second tube, such that the open end of the first tube can slide snugly into the open end of the second tube; and wherein a protrusion on the outer surface of the first tube may slide past a protrusion on the inner surface of the second tube, locking the tubes together;

and wherein the first tube and the second tube each have one or more secondary holes other than the openings at the end of each tube, wherein at least one secondary hole in the first tube may be made coincident with at least one secondary hole in the second tube when the first tube is slid onto the second tube in the unlocked position by rotation of the first and second tubes about their long axes, and

wherein when the first tube is locked onto the second tube at least two secondary holes in the first tube may be made coincident with at least two secondary holes in the second tube by rotation of the first and second tubes about their long axes.

Yang does not disclose a capsule comprising two halves, each having one or more secondary holes, wherein the halves may be rotated around their longitudinal axes to produce both locked and unlocked positions. Yang does not teach the rotation of the two halves to align

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one or more secondary holes for the loading and release of medicament. Furthermore, Yang does not suggest the capsule may be useful in a dry particle inhaler, and does not describe a mechanism which would allow air to flow through the capsule for dispersion and release of the medicament contained in the capsule.

Therefore, Yang does not anticipate claim 28.

Rejection Under 35 U.S.C. § 103

Claim 29 was rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,632,971 to Yang. This rejection is respectfully traversed.

Yang discloses a medicament capsule with raised members on the inner surface of the cap member so as to provide a means of both preventing and subsequently maintaining the final locking position of the capsule. Yang does not teach keying surfaces on the exterior of the medicament capsule.

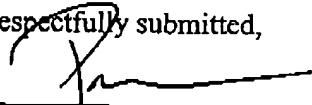
The exterior location serves multiple purposes: it aligns the capsule with the correct orientation *in the chamber of the dry powder inhaler*; it provides a means for visually impaired users to identify the capsule identity (and therefore the encapsulated drug) using tactile perception; and it prevents use of the wrong capsule (and therefore the wrong drug) in an inhaler for delivery of a specific drug, since the wrong capsule, with the wrong keying surface, will not fit in the chamber.

Therefore, Yang does not make obvious claim 29.

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Allowance of claims 28-30 and 41-45, as amended, is respectfully solicited.

Respectfully submitted,



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Certificate of Facsimile Transmission

I hereby certify that this Amendment and Response to Office Action, and any documents referred to as attached therein are being facsimile transmitted on this date, February 20, 2003, to the Commissioner for Patents, U.S. Patent and Trademark Office, Washington, DC 20231.



Patrea Pabst

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MARKED UP VERSION OF AMENDMENTS PURSUANT TO 37 C.F.R. § 1.121

Marked Up Version of Amended Claims**Pursuant to 37 C.F.R. § 1.121(c)(1)(ii)**

28. The capsule of claim 41 comprising a first tube and a second tube, wherein:

(a) a first tube having a long axis, having an inner and an outer surface radial to the long axis, wherein the tube is open at one end perpendicular to the long axis and closed at one end perpendicular to the long axis; and wherein the first tube has at least one protrusion on its outer surface; and

(b) a second tube having a long axis, having an inner and an outer surface radial to the long axis, wherein the tube is open at one end perpendicular to the long axis and closed at one end perpendicular to the long axis and wherein the second tube has at least one protrusion on its inner surface; and wherein the outer circumference of the first tube is approximately equal to the inner circumference of the second tube, such that the open end of the first tube can slide snugly into the open end of the second tube; and wherein a protrusion on the outer surface of the first tube may slide past a protrusion on the inner surface of the second tube, locking the tubes together;

and wherein the first tube and the second tube each have one or more secondary holes other than the openings at the end of each tube, wherein at least one secondary hole in the first tube may be made coincident with at least one secondary hole in the second tube when the first tube is slid onto the second tube in the unlocked position by rotation of the first and second tubes about their long axes, and

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wherein when the first tube is locked onto the second tube at least two secondary holes in the first tube may be made coincident with at least two secondary holes in the second tube by rotation of the first and second tubes about their long axes.

29. The capsule of claim 28 wherein the first and second tubes further comprise keying surfaces at the closed ends of the tubes.

30. The capsule of claim 41 further including medicament selected from the group consisting of liquid, powder, and gaseous medicaments.

41. (Amended) A capsule to contain drug for use in an inhaler comprising a keying surface on an outside surface that is adapted to orient [orients] the capsule within the inhaler or identifies the drug to be placed in the capsule.

42. (amended) The capsule of claim 41 wherein the keying surface is found on the outside of a closed end of the capsule.

43. (Amended) The capsule of claim 41 wherein the keying surface is adapted to orient [orients] the capsule within the inhaler.

44. The capsule of claim 41 wherein the keying surface identifies the drug to be placed in the capsule.

45. (Amended) The capsule of claim 41 comprising a keying surface on the outside of one end which is adapted to orient [orients] the capsule within the inhaler and a keying surface on the outside of the other end which identifies the drug to be placed in the capsule.

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MARKED UP VERSION OF AMENDMENTS PURSUANT TO 37 C.F.R. § 1.121

Clean Version of Amended Claims
Pursuant to 37 C.F.R. § 1.121(c)(1)(ii)

28. The capsule of claim 41 comprising a first tube and a second tube, wherein:

(a) a first tube having a long axis, having an inner and an outer surface radial to the long axis, wherein the tube is open at one end perpendicular to the long axis and closed at one end perpendicular to the long axis; and wherein the first tube has at least one protrusion on its outer surface; and

(b) a second tube having a long axis, having an inner and an outer surface radial to the long axis, wherein the tube is open at one end perpendicular to the long axis and closed at one end perpendicular to the long axis and wherein the second tube has at least one protrusion on its inner surface; and wherein the outer circumference of the first tube is approximately equal to the inner circumference of the second tube, such that the open end of the first tube can slide snugly into the open end of the second tube; and wherein a protrusion on the outer surface of the first tube may slide past a protrusion on the inner surface of the second tube, locking the tubes together;

and wherein the first tube and the second tube each have one or more secondary holes other than the openings at the end of each tube, wherein at least one secondary hole in the first tube may be made coincident with at least one secondary hole in the second tube when the first tube is slid onto the second tube in the unlocked position by rotation of the first and second tubes about their long axes, and

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wherein when the first tube is locked onto the second tube at least two secondary holes in the first tube may be made coincident with at least two secondary holes in the second tube by rotation of the first and second tubes about their long axes.

29. The capsule of claim 28 wherein the first and second tubes further comprise keying surfaces at the closed ends of the tubes.

30. The capsule of claim 41 further including medicament selected from the group consisting of liquid, powder, and gaseous medicaments.

41. (Amended) A capsule to contain drug for use in an inhaler comprising a keying surface on an outside surface that is adapted to orient the capsule within the inhaler or identifies the drug to be placed in the capsule.

42. (amended) The capsule of claim 41 wherein the keying surface is found on the outside of a closed end of the capsule.

43. (Amended) The capsule of claim 41 wherein the keying surface is adapted to orient the capsule within the inhaler.

44. The capsule of claim 41 wherein the keying surface identifies the drug to be placed in the capsule.

45. (Amended) The capsule of claim 41 comprising a keying surface on the outside of one end which is adapted to orient the capsule within the inhaler and a keying surface on the outside of the other end which identifies the drug to be placed in the capsule.

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MARKED UP VERSION OF AMENDMENTS PURSUANT TO 37 C.F.R. § 1.121

**Marked Up Version of Amended Specification Paragraphs
Pursuant to 37 C.F.R. § 1.121(b)(1)(iii)**

On page 21, please delete the two paragraphs beneath the title, "Abstract of the Disclosure," and substitute them with the following paragraph:

[Described is a dry powder inhaler comprising an intake section; a mixing section, and a mouthpiece. The mouthpiece is connected by a swivel joint to the mixing section, and may swivel back onto the intake section and be enclosed by a cover. The intake chamber comprises a special piston with a tapered piston rod and spring, and one or more bleed-through orifices to modulate the flow of air through the device. The intake chamber further optionally comprises a feedback module to generate a tone indicating to the user when the proper rate of airflow has been achieved. The mixing section holds a capsule with holes containing a dry powder medicament, and the cover only can open when the mouthpiece is at a certain angle to the intake section. The mixing section further opens and closes the capsule when the intake section is at a certain angle to the mouthpiece. The mixing section is a Venturi chamber configured by protrusions or spirals to impart a cyclonic flow to air passing through the mixing chamber. The mouthpiece includes a tongue depressor, and a protrusion to contact the lips of the user to tell the user that the DPI is in the correct position. An optional storage section, with a cover, holds additional capsules. The cover for the mouthpiece, and the cover for the storage section may both be transparent, magnifying lenses.]

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Described are capsules to contain a drug for use in an inhaler. The capsules may be two-part capsules where each half [portion] has apertures which may correspond to apertures in the other half [when each half is partially fitted to the other half, and fully fitted to the other half]. The first half fits snugly within the second half and the two halves may be rotated around their longitudinal axes with respect to each other to produce unlocked and locked positions. In the unlocked position, at least one aperture in the first half aligns with at least one aperture in the second half, which permits introduction of a medicament. In the locked position, at least two apertures in the first half align with at least two apertures in the second half, allowing air to pass through the capsule, releasing the medicament contained therein. [All the apertures may be closed when the two halves are rotated around their longitudinal axes with respect to each other.] Each capsule may have a unique key on each half that only fits with a particular inhaler or identifies the medicament contained therein.